

Message

From: Shams, Dahnish [Shams.Dahnish@epa.gov]
Sent: 10/8/2021 2:32:44 PM
To: Kraft, Andrew [Kraft.Andrew@epa.gov]; Glenn, Barbara [Glenn.Barbara@epa.gov]
CC: Thayer, Kris [thayer.kris@epa.gov]; Soto, Vicki [Soto.Vicki@epa.gov]
Subject: FW: IRIS Agency Review (Step 2) - Transmission of the draft IRIS Assessment of Formaldehyde - Inhalation
Attachments: UPDATED_Formaldehyde_MainText_2021AgencyReview Reg4 markup.docx

FYI – Comments from R4.

- Dahnish

Chemical & Pollutant Assessment Division (CPAD)
Center for Public Health and Environmental Assessment (CPHEA)
Office of Research and Development, U.S. EPA
O: (202) 564-2758

From: Koporec, Kevin <Koporec.Kevin@epa.gov>
Sent: Thursday, October 7, 2021 6:11 PM
To: Shams, Dahnish <Shams.Dahnish@epa.gov>
Cc: Frederick, Tim <Frederick.Tim@epa.gov>
Subject: RE: IRIS Agency Review (Step 2) - Transmission of the draft IRIS Assessment of Formaldehyde - Inhalation

Hi Dahnish,

Here is a markup with Region 4 comments. When I was doing the markup, my comments had my name with them, but after I saved the document, the comments all just seem to be labeled as "Author". So, let me know if you need me to state on what pages I have comments.

Thanks,
Kevin

Kevin Koporec
Toxicologist
EPA Region 4
(404)562-8644

From: Shams, Dahnish <Shams.Dahnish@epa.gov>
Sent: Thursday, September 23, 2021 8:17 PM
To: Soto, Vicki <Soto.Vicki@epa.gov>; Miller, GregoryG <Miller.Gregory@epa.gov>; Lowit, Anna <Lowit.Anna@epa.gov>; Gillespie, Andrew <Gillespie.Andrew@epa.gov>; Barone, Stan <Barone.Stan@epa.gov>; Benson, Amy <Benson.Amy@epa.gov>; Raffaele, Kathleen <raffaele.kathleen@epa.gov>; Murphy, Deirdre <Murphy.Deirdre@epa.gov>; Hoyer, Marion <hoyer.marion@epa.gov>; Vasu, Amy <Vasu.Amy@epa.gov>; Saili, Katherine <saili.katherine@epa.gov>; Dockins, Chris <Dockins.Chris@epa.gov>; Dzubow, Rebecca <Dzubow.Rebecca@epa.gov>; Lloyd, Christine <Lloyd.Christine@epa.gov>; Vu, Chau <Vu.Chau@epa.gov>; Gehlhaus, Martin <Gehlhaus.Martin@epa.gov>; Adams, Glenn <Adams.Glenn@epa.gov>; Koporec, Kevin <Koporec.Kevin@epa.gov>; Frederick, Tim <Frederick.Tim@epa.gov>; Sundar, Bhooma <sundar.bhooma@epa.gov>; Benson, Bob <Benson.Bob@epa.gov>; Small, Matthew <Small.Matthew@epa.gov>; Stralka, Daniel <Stralka.Daniel@epa.gov>; Kissinger, Lon <Kissinger.Lon@epa.gov>; Milburn, Anna <Milburn.Anna@epa.gov>; Foster, Stiven <Foster.Stiven@epa.gov>; Pfohl, Marisa <Pfohl.Marisa@epa.gov>; Brinkerhoff, Chris <Brinkerhoff.Chris@epa.gov>;

Blair, Susanna <Blair.Susanna@epa.gov>

Cc: Thayer, Kris <thayer.kris@epa.gov>; Kraft, Andrew <Kraft.Andrew@epa.gov>; Waleko, Garland <Waleko.Garland@epa.gov>; Shirke, Avanti <shirke.avanti@epa.gov>; Avery, James <Avery.James@epa.gov>; Glenn, Barbara <Glenn.Barbara@epa.gov>; Jones, Samantha <Jones.Samantha@epa.gov>; Williams, Ashlei <Williams.Ashlei@epa.gov>

Subject: RE: IRIS Agency Review (Step 2) - Transmission of the draft IRIS Assessment of Formaldehyde - Inhalation

Dear IRIS Agency Reviewers,

The IRIS Program is pleased to share the following updated materials for the formaldehyde (inhalation) assessment on the IRIS Program SharePoint site (see link below):

- Updated Toxicological Review
- Updated Supplemental Materials
- Updated Systematic Evidence Map
- Draft Charge Questions (NEW)

These files incorporate the results of the updated literature search. The Overview document has not been updated. We will update the document after Agency Review is completed. Additionally, we want to note the Appendix is still being cleaned up and HERO IDs are being added/updated. All of the studies synthesized in the main draft to inform the conclusions include HERO IDs (unformatted). Technical editing will occur following Agency Review. Please have your office's consolidated comments placed in the IRIS SharePoint site by **COB October 7, 2021** (https://usepa.sharepoint.com/sites/ORD_Work/IRISagencyreview/SitePages/Home.aspx).

ORD will schedule a meeting to discuss the comments received on October 14th.

If you have any questions about the IRIS formaldehyde-inhalation assessment Agency Review, please don't hesitate to reach out.

Dahnish Shams
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From: Shams, Dahnish

Sent: Friday, September 10, 2021 12:09 PM

To: Soto, Vicki <Soto.Vicki@epa.gov>; Miller, GregoryG <Miller.Gregory@epa.gov>; Lowit, Anna <Lowit.Anna@epa.gov>; Gillespie, Andrew <Gillespie.Andrew@epa.gov>; Barone, Stan <Barone.Stan@epa.gov>; Benson, Amy <Benson.Amy@epa.gov>; Raffaele, Kathleen <raffaele.kathleen@epa.gov>; Murphy, Deirdre <Murphy.Deirdre@epa.gov>; Hoyer, Marion <hoyer.marion@epa.gov>; Vasu, Amy <Vasu.Amy@epa.gov>; Salli, Katherine <salli.katherine@epa.gov>; Dockins, Chris <Dockins.Chris@epa.gov>; Dzubow, Rebecca <Dzubow.Rebecca@epa.gov>; 'Lloyd, Christine' <Lloyd.Christine@epa.gov>; Vu, Chau <Vu.Chau@epa.gov>; Gehlhaus, Martin <Gehlhaus.Martin@epa.gov>; Adams, Glenn <Adams.Glenn@epa.gov>; Koporec, Kevin <Koporec.Kevin@epa.gov>; Frederick, Tim <Frederick.Tim@epa.gov>; Sundar, Bhooma <sundar.bhooma@epa.gov>; Benson, Bob <Benson.Bob@epa.gov>; Small, Matthew <Small.Matthew@epa.gov>; 'Stralka, Daniel' <Stralka.Daniel@epa.gov>; 'Kissinger, Lon' <Kissinger.Lon@epa.gov>; Milburn, Anna <Milburn.Anna@epa.gov>; Foster, Stiven <Foster.Stiven@epa.gov>; Pfohl, Marisa <Pfohl.Marisa@epa.gov>; Brinkerhoff, Chris <Brinkerhoff.Chris@epa.gov>; Blair, Susanna <Blair.Susanna@epa.gov>

Cc: Thayer, Kris <thayer.kris@epa.gov>; Kraft, Andrew <Kraft.Andrew@epa.gov>; Waleko, Garland <Waleko.Garland@epa.gov>; Shirke, Avanti <shirke.avanti@epa.gov>; 'Avery, James' <Avery.James@epa.gov>; Glenn, Barbara <Glenn.Barbara@epa.gov>; Jones, Samantha <Jones.Samantha@epa.gov>; Williams, Ashlei

<Williams.Ashlei@epa.gov>

Subject: RE: IRIS Agency Review (Step 2) - Transmission of the draft IRIS Assessment of Formaldehyde - Inhalation

Dear IRIS Agency Reviewers,

The IRIS Program is working to complete a draft assessment for formaldehyde-inhalation. We have had some unfortunate delays while developing the systematic evidence map (SEM) and are currently aiming to share the draft assessment later than expected, on **September 23, 2021**.

As a result, to maintain the two-week period for review of the redline updates to the draft assessment, we will be extending the Agency Review period through **October 7, 2021**. Following the Agency Review period, ORD will schedule a meeting to discuss the comments received, on or around October 14th.

Additionally, we updated the SEM that was shared on August 26, 2021. Specifically, we added HAWC literature trees that portray the screening decisions for each search, and updated some of the reference counts. Although the content of the SEM has not changed, some reviewers may wish to download the updated draft from the SharePoint site: (https://usepa.sharepoint.com/sites/ORD_Work/IRISAgencyreview/SitePages/Home.aspx)

If you have any questions about the IRIS formaldehyde-inhalation assessment Agency Review, please don't hesitate to reach out.

Dahnish

Dahnish Shams
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Center for Public Health and Environmental Assessment (CPHEA)
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From: Shams, Dahnish

Sent: Thursday, August 26, 2021 11:22 AM

To: Soto, Vicki <Soto.Vicki@epa.gov>; Miller, GregoryG <Miller.Gregory@epa.gov>; Lowit, Anna <Lowit.Anna@epa.gov>; Gillespie, Andrew <Gillespie.Andrew@epa.gov>; Barone, Stan <Barone.Stan@epa.gov>; Benson, Amy <Benson.Amy@epa.gov>; Raffaele, Kathleen <raffaele.kathleen@epa.gov>; Murphy, Deirdre <Murphy.Deirdre@epa.gov>; Hoyer, Marion <hoyer.marion@epa.gov>; Vasu, Amy <Vasu.Amy@epa.gov>; Saili, Katherine <saili.katherine@epa.gov>; Dockins, Chris <Dockins.Chris@epa.gov>; Dzubow, Rebecca <Dzubow.Rebecca@epa.gov>; Lloyd, Christine <Lloyd.Christine@epa.gov>; Vu, Chau <Vu.Chau@epa.gov>; Gehlhaus, Martin <Gehlhaus.Martin@epa.gov>; Adams, Glenn <Adams.Glenn@epa.gov>; Koporec, Kevin <Koporec.Kevin@epa.gov>; Frederick, Tim <Frederick.Tim@epa.gov>; Sundar, Bhooma <sundar.bhooma@epa.gov>; Benson, Bob <Benson.Bob@epa.gov>; Small, Matthew <Small.Matthew@epa.gov>; Stralka, Daniel <Stralka.Daniel@epa.gov>; Kissinger, Lon <Kissinger.Lon@epa.gov>; Milburn, Anna <Milburn.Anna@epa.gov>
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Subject: RE: IRIS Agency Review (Step 2) - Transmission of the draft IRIS Assessment of Formaldehyde - Inhalation

Dear IRIS Agency Reviewers –

We are pleased to provide the **Systematic Evidence Map (SEM) for Formaldehyde** for Agency review. The SEM was developed to identify any new literature published since the original draft assessment.

As a reminder, the IRIS program will be sharing an updated draft assessment on **September 10, 2021**. Agency reviewers will be given two weeks to consider the edits made in the updated draft to address potentially impactful new studies.

We are sharing documents on the IRIS Agency Review SharePoint site:

https://usepa.sharepoint.com/sites/ORD_Work/IRISAgencyreview/SitePages/Home.aspx (see the [Review Documents](#) section). The SharePoint folder includes the 2017 original draft assessment materials (draft toxicological review, appendices, and an assessment overview), as well as the SEM.

A few notes on this review are provided below:

- All comments should be posted to the SharePoint site no later than **COB Friday, September 24, 2021**. Following the conclusion of the review period, the IRIS Program will convene an Agency Review meeting (no Interagency partners) to discuss major comments.
- Please combine all comments from an office or region into a single document, then upload to the Formaldehyde Agency Review 2021 folder on the SharePoint site.

Thank you for your participation in EPA's IRIS Program. We appreciate your scientific input on IRIS documents. Please let us know if you have any questions.

Dahnish

Dahnish Shams
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From: Soto, Vicki <Soto.Vicki@epa.gov>

Sent: Thursday, August 19, 2021 5:26 PM

To: Shams, Dahnish <Shams.Dahnish@epa.gov>; Miller, GregoryG <Miller.Gregory@epa.gov>; Lowit, Anna <Lowit.Anna@epa.gov>; Gillespie, Andrew <Gillespie.Andrew@epa.gov>; Barone, Stan <Barone.Stan@epa.gov>; Benson, Amy <Benson.Amy@epa.gov>; Raffaele, Kathleen <raffaele.kathleen@epa.gov>; Murphy, Deirdre <Murphy.Deirdre@epa.gov>; Hoyer, Marion <hoyer.marion@epa.gov>; Vasu, Amy <Vasu.Amy@epa.gov>; Saili, Katherine <saili.katherine@epa.gov>; Dockins, Chris <Dockins.Chris@epa.gov>; Dzubow, Rebecca <Dzubow.Rebecca@epa.gov>; Lloyd, Christine <Lloyd.Christine@epa.gov>; Vu, Chau <Vu.Chau@epa.gov>; Gehlhaus, Martin <Gehlhaus.Martin@epa.gov>; Adams, Glenn <Adams.Glenn@epa.gov>; Koporec, Kevin <Koporec.Kevin@epa.gov>; Frederick, Tim <Frederick.Tim@epa.gov>; Sundar, Bhooma <sundar.bhooma@epa.gov>; Benson, Bob <Benson.Bob@epa.gov>; Small, Matthew <Small.Matthew@epa.gov>; Stralka, Daniel <Stralka.Daniel@epa.gov>; Kissinger, Lon <Kissinger.Lon@epa.gov>; Milburn, Anna <Milburn.Anna@epa.gov>

Cc: Thayer, Kris <thayer.kris@epa.gov>; Kraft, Andrew <Kraft.Andrew@epa.gov>; Waleko, Garland <Waleko.Garland@epa.gov>; Shirke, Avanti <shirke.avanti@epa.gov>; Avery, James <Avery.James@epa.gov>; Glenn, Barbara <Glenn.Barbara@epa.gov>; Jones, Samantha <Jones.Samantha@epa.gov>; Williams, Ashlei <Williams.Ashlei@epa.gov>

Subject: RE: IRIS Agency Review (Step 2) - Transmission of the draft IRIS Assessment of Formaldehyde - Inhalation

Dear IRIS Agency Reviewers,

The IRIS Program is working to complete an updated systematic evidence map (SEM) for formaldehyde. The SEM is being developed to identify any new literature published since the suspended 2017 draft assessment. We have had some unfortunate delays and are currently aiming to share the draft SEM a week later than expected, on **August 26th**, followed by the updated draft assessment (with redline changes based on the new literature) on **September 10th**.

As a result, we will be extending the Agency Review period through **September 24, 2021**. Following the Agency Review period, ORD will schedule a meeting to discuss the comments received.

If you have any questions about the formaldehyde Agency Review, please don't hesitate to reach out.

Thank you,
Vicki

Vicki Soto, PMP (she/her/hers)
Associate Director (Acting)
ORD/CPHEA/CPAD
Soto.vicki@epa.gov
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571-982-2819 (cell)

From: Soto, Vicki <Soto.Vicki@epa.gov>

Sent: Thursday, July 22, 2021 11:52 AM

To: Shams, Dahnish <Shams.Dahnish@epa.gov>; Miller, GregoryG <Miller.Gregory@epa.gov>; Lowit, Anna <Lowit.Anna@epa.gov>; Gillespie, Andrew <Gillespie.Andrew@epa.gov>; Barone, Stan <Barone.Stan@epa.gov>; Benson, Amy <Benson.Amy@epa.gov>; Raffaele, Kathleen <raffaele.kathleen@epa.gov>; Murphy, Deirdre <Murphy.Deirdre@epa.gov>; Hoyer, Marion <hoyer.marion@epa.gov>; Vasu, Amy <Vasu.Amy@epa.gov>; Saili, Katherine <saili.katherine@epa.gov>; Dockins, Chris <Dockins.Chris@epa.gov>; Dzubow, Rebecca <Dzubow.Rebecca@epa.gov>; Lloyd, Christine <Lloyd.Christine@epa.gov>; Vu, Chau <Vu.Chau@epa.gov>; Gehlhaus, Martin <Gehlhaus.Martin@epa.gov>; Adams, Glenn <Adams.Glenn@epa.gov>; Koporec, Kevin <Koporec.Kevin@epa.gov>; Frederick, Tim <Frederick.Tim@epa.gov>; Sundar, Bhooma <sundar.bhooma@epa.gov>; Benson, Bob <Benson.Bob@epa.gov>; Small, Matthew <Small.Matthew@epa.gov>; Stralka, Daniel <Stralka.Daniel@epa.gov>; Kissinger, Lon <Kissinger.Lon@epa.gov>; Milburn, Anna <Milburn.Anna@epa.gov>
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Subject: RE: IRIS Agency Review (Step 2) - Transmission of the draft IRIS Assessment of Formaldehyde - Inhalation

Dear IRIS Agency Reviewers,

As noted by ORD in June, the IRIS Program is working to complete an updated systematic evidence map (SEM) for formaldehyde. The SEM is being developed to identify any new literature published since the original draft assessment. Unfortunately, due to unexpected staffing delays (e.g., jury duty), we are now currently aiming to share the draft SEM by **August 16**, followed by an updated draft assessment on **August 30**.

As a result, we will be extending the Agency Review period from August 6, 2021 to **September 13, 2021**. Following the Agency Review period, ORD will schedule a meeting to discuss the comments received.

If you have any questions about the formaldehyde Agency Review, please don't hesitate to reach out.

Thank you,
Vicki

Vicki Soto, PMP (she/her/hers) | 202-564-3077 | soto.vicki@epa.gov
ORD/CPHEA/CPAD

Mailing Address:
USEPA Headquarters | William Jefferson Clinton Building | 1200 Pennsylvania Avenue, N.W. | MC: 8602R | Washington, DC 20460

From: Shams, Dahnish <Shams.Dahnish@epa.gov>

Sent: Friday, June 11, 2021 3:18 PM

To: Miller, GregoryG <Miller.Gregory@epa.gov>; Lowit, Anna <Lowit.Anna@epa.gov>; Gillespie, Andrew <Gillespie.Andrew@epa.gov>; Barone, Stan <Barone.Stan@epa.gov>; Benson, Amy <Benson.Amy@epa.gov>; Raffaele, Kathleen <raffaele.kathleen@epa.gov>; Murphy, Deirdre <Murphy.Deirdre@epa.gov>; Hoyer, Marion <hoyer.marion@epa.gov>; Vasu, Amy <Vasu.Amy@epa.gov>; Saili, Katherine <saili.katherine@epa.gov>; Dockins, Chris <Dockins.Chris@epa.gov>; Dzubow, Rebecca <Dzubow.Rebecca@epa.gov>; Lloyd, Christine <Lloyd.Christine@epa.gov>; Vu, Chau <Vu.Chau@epa.gov>; Gehlhaus, Martin <Gehlhaus.Martin@epa.gov>; Adams, Glenn <Adams.Glenn@epa.gov>; Koporec, Kevin <Koporec.Kevin@epa.gov>; Frederick, Tim <Frederick.Tim@epa.gov>; Sundar, Bhooma <sundar.bhooma@epa.gov>; Benson, Bob <Benson.Bob@epa.gov>; Small, Matthew <Small.Matthew@epa.gov>; Stralka, Daniel <Stralka.Daniel@epa.gov>; Kissinger, Lon <Kissinger.Lon@epa.gov>; Milburn, Anna <Milburn.Anna@epa.gov>

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Subject: IRIS Agency Review (Step 2) - Transmission of the draft IRIS Assessment of Formaldehyde - Inhalation

Dear IRIS Agency Reviewers –

We are pleased to provide the **draft IRIS Toxicological Review of Formaldehyde - Inhalation** for Agency review. For this assessment, we will be conducting Agency review over approximately two months, as compared to the typical 1-month review period. Herein, the IRIS Program is providing for your review and comment the original draft assessment materials developed and shared with EPA/OCSPP/OPPT in 2018 to inform their TSCA risk evaluation.

In addition to this draft, the IRIS program is developing a systematic evidence map to identify any new literature published since the original draft. The IRIS program anticipates sharing the evidence map in early July 2021, as well as an updated draft assessment in mid July 2021. Agency reviewers will be given no less than two weeks to consider the edits made in the updated draft to address potentially impactful new studies.

An EPA-wide briefing to introduce the IRIS Assessment of Formaldehyde and the process for Agency Review is currently scheduled for June 24, 2021.

We are sharing documents on the IRIS Agency Review SharePoint site:

https://usepa.sharepoint.com/sites/ORD_Work/IRISagencyreview/SitePages/Home.aspx (see the Review Documents section). The SharePoint folder includes the draft toxicological review, appendices, and an assessment overview. The assessment overview was developed specifically for this assessment to provide a summary of all major conclusions and the primary supporting rationale for each decision.

A few notes on this review are provided below:

- All comments should be posted to the SharePoint site no later than **COB Friday, August 6, 2021** (dependent on timing of release of the updated draft assessment). Following the conclusion of the review period, the IRIS Program will convene an Agency Review meeting (no Interagency partners) to discuss major comments. This meeting is tentatively scheduled for August 11, 2021.
- Please combine all comments from an office or region into a single document, then upload to the Formaldehyde Agency Review 2021 folder on the SharePoint site. Only the Agency Reviewers listed below have access to the site. If other staff wish to gain access to the site, please send a request through SharePoint.

Thank you for your participation in EPA's IRIS Program. We appreciate your scientific input on IRIS documents. Please let us know if you have any questions.

Dahnish

List of IRIS Agency Reviewers

Office of Water - Greg Miller

Office of Chemical Safety and Pollution Prevention

- **Office of Pesticide Programs** - Anna Lowit
- **Office of Pollution Prevention and Toxics** – Andrew Gillespie, Stan Barone, Amy Benson

Office of Land and Emergency Management - Kathleen Raffaele

Office of Air and Radiation - Deirdre Murphy

- **Office of Transportation and Air Quality** - Marion Hoyer
- **Office of Air Quality Planning and Standards** - Amy Vasu and Katherine Saili

Office of Policy - Chris Dockins

Office of Children's Health Protection - Rebecca Dzubow and Christine Lloyd

Region 1 – Chau Vu

Region 2 - Marion Olsen

Region 3 - Martin Gehlhaus

Region 4 - Glenn Adams, Kevin Koporec, and Tim Frederick

Region 5 – Bhooma Sundar

Region 6 - Anna Milburn

Region 7 - Kelly Schumacher

Region 8 - Bob Benson

Region 9 - Matt Small and Dan Stralka

Region 10 - Lon Kissinger

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